REMARKS

Prior to entry of this Amendment, Claims 1-8 were pending. With this Amendment, Claims 4 and 23 are being amended and Claim 9 is being added. Reconsideration of the claims in light of the following remarks is requested.

Specification

The specification has been amended at page 3, line 10 to correct a minor clerical error. Specifically the phrase "Figures 3A, 3B, 3C and 3D" has been amended to add the term "3D". Support for the term "3D" is found at the last sentence of the paragraph at page 3, lines 16-17. Accordingly, the present amendment does not present new matter.

The Amendments of the Claims

Claim Objection

Claim 4 is objected to because of informality with the abbreviation "EFS." Applicants have corrected this informality by amending Claim 4 to add the phase "electroconduit-forming species". Support for the amendment is found on page 2, line 20. Accordingly, the present amendment does not present new matter and entry is proper.

Newly Added Claim

Claim 4, is dependent on Claim 1, and is being newly added. Claim 4 finds support throughout the application as originally filed and therefore does not present new matter (see, e.g., the disclosure at page 6, lines 4 through 11, and Figure 3).

Claim Rejection Under 35 USC §102(e)

Claims 1-8 are rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Duong *et al.* (U.S. Patent No. 6,740,518 B1). The rejection is traversed as applied to Claims 1-8 on the ground that the cited reference fails to teach each and every limitation of the rejected claims.

To anticipate a claim under 35 U.S.C. §102(e), a reference must teach every element of the rejected claim (MPEP §2131). The Patent Office alleges that, among other things, Duong *et al.* disclose applying an initiation signal (i.e., an input waveform) to a tissue collection device (ie., a circuit board) comprising an electrode comprising a self-assembled monolayer and an assay complex comprising a capture binding ligand, said target analyte, and an electron transfer moiety as recited in claim 1. (Office Action, at page 3, ((emphasis added)).

Claim 1 of the instant application is directed, in part, to "applying an initiation signal to a tissue collection device comprising an electrode". The remaining pending rejected claims (Claims 2-8) ultimately depend from Claim 1 and therefore also include "a tissue collection device". The specification states that a "tissue collection device" is any container, generally capable of being sealed, that can be used to collect, contain or store tissues, including bodily fluids (Specification at page 6, lines 4-5). Duong *et al.* does not teach or suggest a "tissue collection device", and hence, Duong *et al.* does not anticipate these claimed subject matter.

Accordingly, since the cited reference fails to teach each and every limitation of the pending rejected Claims, Applicants request that the rejection of Claims 1-8 under 35 U.S.C. §102(e) be withdrawn.

Claim Rejection Under 35 USC §102(f)

Claims 1-8 are rejected under 35 U.S.C. §102(f) as allegedly the applicant did not invent the claimed subject matter. The rejection is traversed as applied to Claims 1-8 on the ground that the cited reference fails to teach each and every limitation of the rejected claims. As described above, Duong *et al.* does not teach or suggest a "tissue collection device", and hence, Duong *et al.* fails to teach each and every limitation of the rejected claims. Accordingly, since the cited reference fails to teach each and every limitation of the pending rejected Claims, Applicants request that the rejection of Claims 1-8 under 35 U.S.C. §102(f) be withdrawn.

Double Patenting Rejection

Claims 1 and 5 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1, 2, and 13 of Duong *et al.* (U.S. Patent No, 6,740,518 B1) in view of Rubinstein *et al.* (U.S. Patent No: 5,108, 573). As a preliminary matter, Applicants submit, that in determining whether a non-statutory basis exists for a double patenting rejection, the question is whether any claim in the instant application defines an invention that is merely an obvious variation of an invention claimed in a patent. See M.P.E.P. §804. An obviousness-type double patenting rejection is analogous to the obviousness rejection based on 35 U.S.C. §103, except that only the claims in the cited patents or applications are considered prior art. See M.P.E.P. §804. Therefore, the analysis employed in an obviousness-type double patenting rejection parallels the analysis of a 35 U.S.C. §103 obviousness determination, and a

prima facie case of obviousness must be established. See *In re Braat,* 937 F.2d 589, 19 USPQ2d 1289 (Fed. Cir. 1991).

Claim 1 of the instant application is directed, in part, to "applying an initiation signal to a tissue collection device comprising an electrode". Claim 5 is a dependent claim of Claim 1. As the Examiner is aware, to make a prima facie case of obviousness, all claim limitations must be taught or suggested in prior art. See M.P.E.P. §2143.03. Claims 1, 2, and 13 of Duong *et al.* and the claims of Rubinstein *et al.* neither teach nor suggest applying an initiation signal to a tissue collection device comprising an electrode. Since not every limitation in the present claims are taught or suggested, a prima facie case of obviousness for double patenting rejection has not been established.

Applicants accordingly submit that Claims 1 and 5 of the present application are not obvious variations of the claims in the cited patents and request the double-patenting rejection be withdrawn.

CONCLUSION

Applicants respectfully submit that the claims are now in condition for allowance and early notification to that effect is respectfully requested. If the Examiner feels there are further unresolved issues, the Examiner is respectfully requested to phone the undersigned at (415) 781-1989.

Respectfully submitted,
DORSEY & WHITNEY LLP

Dated: 1/10/05 By: Renee M Kosslak
Renee M. Kosslak, Reg. No. 47,717 for
Robin M. Silva, Reg. No. 38,304

Customer No.: 32940
Four Embarcadero Center
Suite 3400
San Francisco, CA 94111-4187
Telephone: (415) 781-1989
Facsimile: (415) 398-3249